

REMARKS

Favorable reconsideration, reexamination, and allowance of the present patent application are respectfully requested in view of the foregoing amendments and the following remarks.

Personal Interview

Applicant and the undersigned wish to thank Mr. Bui for the courteous and productive interview conducted on 9 December 2005 with Applicant's local representative, Mr. Adam Cermak. Because Applicant was not relieved of the duty under 37 C.F.R. § 1.33(b) of providing a summary of the arguments presented during that interview, Applicant provides the following comments.

The interview started with a brief explanation of *Fischell*, and more specifically that his undulating S-struts 16 are intended by *Fischell* to maintain their shape after an initial expansion of the stent. This is so that, if part of the stent obstructs a branching artery, as illustrated in Figs. 4A and 5, another balloon catheter can be pushed through the wall of the stent (Fig. 4B) and expanded (Fig. 4c) to push the S-strut and diagonal struts 14 out of the way (Figs. 4D, 6). Mr. Cermak explained that to *Fischell* this was a very important aspect of the disclosure.

Concerning *Jang*, Mr. Cermak pointed out that the patent appears to include no explanation of why the particular structures were chosen. Mr. Cermak then explained that, assuming *arguendo* that a skilled artisan were to find motivation to combine *Jang* with *Fischell*, one would arrive at a configuration of *Fischell*'s S-struts different from the drawing appearing at page 5 of the Office Action; that is, a substitution of *Jang*'s connecting struts for *Fischell*'s undulating S-struts would result in connecting struts that only cross the midline of *Fischell*'s diagonal struts 13 once. Mr. Cermak pointed out to Mr. Bui that Claims 5 and 10 require, *inter alia*, that bridging elements cross that midline three times, and showed Mr. Bui a drawing, similar to that appearing at page 5 of the Office Action, in which the *Jang* connecting struts were superimposed on *Fischell*'s device, and thus showed that the hypothetical *Fischell/Jang* device would only cross the midline once.

Mr. Cermak also pointed out that nowhere does *Jang* disclose that his connecting column

struts are thinner than his expanding column struts, and that the drawings are probably 'not to scale'.

Rejection under 35 U.S.C. § 102

In the Office Action, beginning at page 2, Claims 1-9 were rejected under 35 U.S.C. § 102(e), as reciting subject matters that allegedly are anticipated by U.S. Patent No. 6,235,053, issued to Jang. Applicant respectfully requests reconsideration of this rejection.

This application describes devices and methods embodying principles of the present invention. As described throughout this application, and illustrated in the drawing figures, a stent 20, 80 in accordance with the present invention includes S-shaped bridging elements 84, which connect together cylindrical tubes 82. As discussed in the present specification, *e.g.*, at paragraph [0056]:

The bridging elements 84 allow the tissue supporting device to bend axially when passing through the tortuous path of the vasculature to the deployment site and allow the device to bend when necessary to match the curvature of a lumen to be supported. The S-shaped bridging elements 84 provide improved axial flexibility over prior art devices due to the thickness of the elements in the radial direction which allows the width of the elements to be relatively small without sacrificing radial strength. For example, the width of the bridging elements 84 may be about 0.0012-0.0013 inches (0.0305-0.0330 mm).

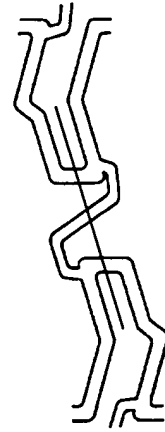
The configuration of the S-shaped bridging elements provides flexibility between the tubes 82 such that the stent can flex in all directions.

Claim 1 relates to an expandable medical device having a combination of elements including, *inter alia*, a plurality of S-shaped bridging elements connected between interconnected ends of struts in adjacent cylindrical tubes, wherein the bridging elements are connected entirely above a midline of V-shapes on one cylindrical tube and entirely below the midline of V-shapes on an adjacent cylindrical tube, wherein the bridging elements cross the midline of the V-shapes three times.

The prior art, including *Jang*, fails to identically disclose or describe a device having the

claimed combination of elements.

Jang describes (see Fig. 1) a tubular stent 10 including expansion columns 32', 32'', each formed of a set of expansion struts, and connecting columns 34', 34'', each formed of a set of connecting struts. One of *Jang*'s connecting strut sets, connecting together two opposing sets of *Jang*'s expansion strut sets, is reproduced herein. The connecting strut set, formed of struts 66', 68', 74', 72', 70' (see Fig. 2) extend diagonally from one side of one expansion strut set to the other side of an opposed expansion strut set. The reproduction herein of *Jang*'s strut configuration has been annotated with a simple, superimposed line which shows that a midline of *Jang*'s expansion strut sets crosses *Jang*'s connecting strut set only once. Accordingly, *Jang* fails to describe a device including each and every element recited in the combinations of Claims 1-9.



Jang's expanding strut sets and connecting strut sets

For at least the foregoing reasons, Applicant respectfully submits that the subject matters of Claims 1-9 are not anticipated by *Jang*, are therefore not unpatentable under 35 U.S.C. § 102, and therefore respectfully requests withdrawal of the rejection thereof under 35 U.S.C. § 102.

Rejection under 35 U.S.C. § 103(a)

In the Office Action, beginning at page 4, Claims 10-16 were rejected under 35 U.S.C. § 103(a), as reciting subject matters that allegedly are obvious, and therefore allegedly unpatentable, over the disclosure of U.S. Patent No. 5,697,971, issued to Fischell *et al.* ("Fischell") in view of *Jang*. Applicant respectfully requests reconsideration of this rejection.

Applicant has, in rebutting the rejection of Claims 1-9 over *Jang, supra*, discussed certain aspects of the present invention.

Claim 10 relates to an expandable medical device having a combination of elements including, *inter alia*, a plurality of S-shaped bridging elements connected between interconnected ends of struts in adjacent cylindrical tubes, wherein each of the bridging elements cross a midline of the V-shapes three times and are connected entirely above the midline of the

V-shapes on one cylindrical tube and entirely below the midline of the V-shapes on an adjacent cylindrical tube.

The prior art, including *Fischell* and *Jang*, fails to disclose, describe, or suggest the combinations of elements recited in Claims 10-16.

As discussed above, *Fischell* teaches away from a modification of his S-struts 16 in the way proposed in the Office Action. *Fischell* describes undulating S-struts 16 forming expandable cells 12, 12'. The purpose of *Fischell*'s expandable cells 12, 12', to remain expandable after deployment of the stent *in vivo*, is explained throughout *Fischell*:

A second type of cell is designed to provide increased longitudinal flexibility prior, to stent deployment and after stent deployment into a main artery, the second type of cell can be readily balloon expanded at the ostium of a side branch artery to a comparatively large diameter without breaking any of the struts of the stent cell. By this technique, unobstructed blood flow into the side branch can be provided.

(col. 1, lines 32-39)

a second type of cell provides increased flexibility prior to deployment and after deployment that cell can be balloon expanded into a generally circular shape thereby causing all stent struts to be moved away from the opening of a side branch of a main artery.

(col. 1, lines 45-48)

Therefore as compared to a cell 11', not only is it easier to expand a cell 12' by placing a balloon within that cell and inflating that balloon to a high pressure, but any cell 12' is also expandable to a greater diameter as compared to any cell 11'.

(col. 3, lines 16-20)

Fischell goes on, beginning at column 3, line 23, to describe Figs. 4A-6. In summary, deployment of a stent in the patient's vasculature at the location of a branch artery can partially block that branch artery (Figs. 1, 4A, 5) with the stent itself. Thus, *Fischell* specifically designed his stent structure so that it includes S-struts 16 which remain laterally (circumferentially) expandable after deployment of the stent, as shown in Fig. 3, so that a balloon can be pushed

through the stent's strut structure at a cell 12, 12' (see Figs. 4B, 4C) and expanded to push the theretofore unexpanded S-struts 16 away from the branch artery (Figs. 4D, 6). Thus, *Fischell* teaches strongly away from any modification of his stent's strut configuration which would impair the ability to unblock branch arteries.

The hypothetical construct alleged to be obvious in the Office Action would, however, do just that: modify *Fischell*'s undulating S-struts, by replacing them with *Jang*'s straighter connecting struts, such that they would have limited or no additional expandability after deployment of the stent in the patient's vasculature. The hypothetical combination of *Fischell* with *Jang* therefore would destroy *Fischell*'s device's functionality for its intended purpose. Applicant respectfully submits that a person of ordinary skill in the art would not seek to emasculate *Fischell*'s stent by modifying it in view of *Jang*.

Assuming, *arguendo*, that the skilled artisan would, despite the fact that *Fischell* strongly teaches away from a combination with *Jang*, look to modify *Fischell*'s stent structure with *Jang*'s connecting column's strut sets (described above), the resulting hypothetical stent would still not include each and every element recited in the combinations of the

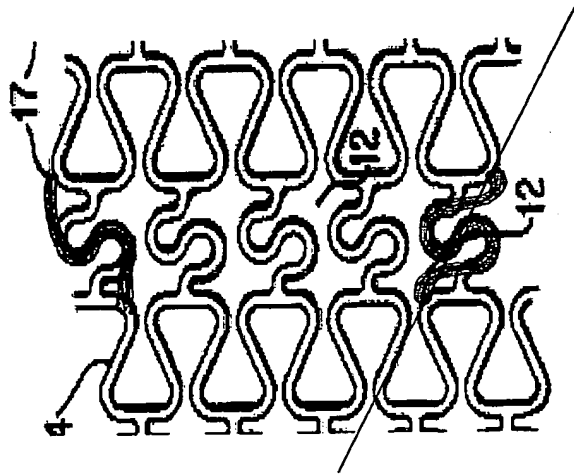


Illustration from pg. 5 of the Office Action, with Applicant's illustration

pending claims. The Office Action kindly includes, at page 5, a marked-up portion of figure 2 of *Fischell*, annotated with a modified S-strut and a diagonal line. Applicant includes a reproduction of that illustration herein, which also includes an alternative illustration described below. Applicant respectfully submits that the illustration contained on page 5 of the Office Action would not be the stent structure the skilled artisan would arrive at from a full and fair reading of *Fischell* and *Jang*, were the routineer to be motivated to combine the two documents. Instead, the illustration on page 5 is the result of an impermissible hindsight reconstruction of the claimed subject matter

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using Applicant's own specification as a guide, and therefore a *prima facie* case of obviousness has not been made.

As discussed during the interview, were one of ordinary skill in the art to combine *Fischell* with *Jang*, the result would be a *Fischell* stent with *Jang* connecting column strut sets. That is, instead of becoming more undulating, as suggested in the page 5 illustration in the Office Action (the right-side illustration reproduced above), the result would be a less serpentine S-strut which extends diagonally between *Fischell*'s struts 13, 14 only once (the left-side illustration reproduced above), as does *Jang*'s connecting strut sets. Nowhere in *Fischell*, *Jang*, or any other evidence in the record, is there motivation to make *Fischell*'s S-struts more serpentine, and indeed *Jang* specifically teaches away from that configuration by disclosing less serpentine elements. Accordingly, Applicant respectfully submits that a *prima facie* case of obviousness has not been made in the Office Action.

For at least the foregoing reasons, Applicant respectfully submits that the subject matters of Claims 10-16, each taken as a whole, would not have been obvious to one of ordinary skill in the art at the time of Applicant's invention, are therefore not unpatentable under 35 U.S.C. § 103(a), and therefore respectfully requests withdrawal of the rejection thereof under 35 U.S.C. § 103(a).


Conclusion

Applicant respectfully submits that the present patent application is in condition for allowance. An early indication of the allowability of this patent application is therefore respectfully solicited.

If Mr. Bui believes that a telephone conference with the undersigned would expedite passage of this patent application to issue, he is invited to call on the number below.

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. If, however, additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and the Commissioner is hereby authorized to charge fees necessitated by this paper, and to credit all refunds and overpayments, to our Deposit Account 50-3100.

Respectfully submitted,

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Date: January 4, 2006